

<b>Case Number:</b>	CM15-0184454		
<b>Date Assigned:</b>	09/24/2015	<b>Date of Injury:</b>	04/07/1997
<b>Decision Date:</b>	11/02/2015	<b>UR Denial Date:</b>	09/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/18/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: North Carolina  
 Certification(s)/Specialty: Family Practice

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 64-year-old male, with a reported date of injury of 04-07-1997. The diagnoses include myalgia and myositis, multi-site osteoarthritis, and extrapyramidal disease. Treatments and evaluation to date have included Anaprox (since at least 02-2015), Flurbiprofen (since at least 02-2015), Cyclobenzaprine, and Tramadol. The diagnostic studies to date have included a urine drug screen on 07-08-2015, which was positive for Tramadol and a tricyclic antidepressant; a urine drug screen on 04-08-2015, which was positive for Tramadol and a tricyclic antidepressant; and a urine drug screen on 02-25-2015, which was positive for Tramadol and a tricyclic antidepressant. The progress report dated 07-08-2015 indicates that the injured worker continued to have total body pain, chronic fatigue, and problems sleeping. It was noted that he was doing well on medication and a regular exercise program. The injured worker had reflux and dyspepsia (indigestion). The objective findings included no new joint swelling, a normal neurological examination, and no rheumatoid arthritis deformities. The treatment plan included the continuation of Naprosyn (Naproxen), topical Flurbiprofen, and the addition of Prilosec for indigestion. The injured worker has been instructed to remain off work until the next office visit. The medical records included a prescription for Flurbiprofen 25%-Lidocaine 5%-Menthol 5%-Camphor 1% 180 grams. The treating physician requested Omeprazole 20mg #60 (date of service: 07-08-2015), Naproxen Sodium 550mg #60 (date of service: 07-08-2015), and Topical Flurbiprofen Power-Lidocaine Powder-Menthol Crystals-Camphor-Alba-derm base cream (date of service: 07-08-2015). On 09-08-2015, Utilization Review (UR) non-certified the request for Omeprazole 20mg #60 (date of service: 07-08-2015), Naproxen Sodium 550mg #60

(date of service: 07-08-2015), and Topical Flurbiprofen Power-Lidocaine Powder-Menthol Crystals-Camphor-Alba-derm base cream (date of service: 07-08-2015).

### **IMR ISSUES, DECISIONS AND RATIONALES**

The Final Determination was based on decisions for the disputed items/services set forth below:

#### **Omeprazole 20mg #60 for DOS 7/8/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** The California chronic pain medical treatment guidelines section on NSAID therapy and proton pump inhibitors (PPI) states: Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastro duodenal lesions. Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.). Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 ug four times daily); or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. There is no documentation provided that places this patient at intermediate or high risk that would justify the use of a PPI. There is no mention of current gastrointestinal or cardiovascular disease. For these reasons, the criteria set forth above per the California MTUS for the use of this medication has not been met. Therefore, the request is not medically necessary.

#### **Naproxen Sodium 550mg #60 with 2 refills for DOS 7/8/15: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** The California chronic pain medical treatment guidelines section on NSAID therapy states: Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular

risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. This medication is recommended for the shortest period of time and at the lowest dose possible. The dosing of this medication is within the California MTUS guideline recommendations. The definition of shortest period possible is not clearly defined in the California MTUS. Therefore, the request is medically necessary.

**Topical Flurbiprofen powder, Lidocaine powder, Menthol crystals, Camphor, Albaderm base cream for DOS 7/8/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The requested medication contains ingredients, which are not indicated per the California MTUS for topical analgesic use. Therefore, the request is not medically necessary.